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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,516	10/02/2001	Alan W. Faull	ASZD-P01-470	5215

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EXAMINER

ROBINSON, BINTA M

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 08/12/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Applicant No.	Applicant(s)
	09/889,516	FAULL ET AL.
Examiner	Art Unit	
Binta M. Robinson	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-10 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \*    c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7-9</u> .	6) <input type="checkbox"/> Other: _____.

### **Detailed Action**

Claims 1-6 provide for the use of the compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F.

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not provide enablement for R1 equal to all heteroaryl rings, R8 equal to all heteroaryl rings, R14 equal to all heteroaryl groups, R15 equal to all heteroaryl rings, R16 equal to all heteroaryl rings, R17 and R18 independently equal to all heteroaryl rings, R17 and R18 coming together with the nitrogen atom to which they are attached to form all optionally substituted heterocyclic rings which optionally contain further heteroatoms, or R9 equal to all substituted heteroaryl rings, R4-R7 equal to all

functional groups, or all optionally substituted heterocyclic groups, and R19 and R20 coming together with the atom to which they are attached to form all optionally substituted heterocycll rings which optionally contains further heteroatoms such as S(O)n, oxygen, and nitrogen. Claim(s) 1-10 are also rejected under 35 U.S.C. 112, first paragraph specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Inhibition of monocyte chemoattractant protein=1 and/or RANTES induced chemotaxis is a mechanism not a disease. The disease being treated by this inhibition is not stated. The specification must contain one practical utility in currently available form. The inhibition of an enzyme must be related to a disease that needs to be improved and this disease needs to be recited. There is no reasonable assurance that these compounds will have all of the alleged properties or have the applicants supplied the supporting data. The applicant is referred to *In re Fouche* 169 USPQ 429 CCPA, 1971, MPEP 716.02 B. The applicant is referred to *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte Foreman* 230 USPQ 546 (Bd. Of App. And Interv 1986).

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine

experimentation. The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in Ex parte Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1)the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of the breadth of the claims, R1, R8, R14, R15, R16, R17, R18, R17 and R9, R4-R7, R19 and R20 encompasses a much wider Markush grouping of radicals than those radicals synthesized. In terms of the second Wands factor, the nature of the invention is that these compounds are antinflammatory agents. The level of predictability in the art of these compounds is low, since none of these compounds are tested for their effects on the inhibition of monocyte chemoattract protein-1 and/or RANTES induced chemotaxis. Additionally, no compounds were tested or synthesized where R1, R8, R14, , R19, R20, R4-R7 equal to the heteroaryl rings claimed, and R19 and R20 coming together to form the heteroaryl rings claimed. In terms of the sixth Wands factor, the amount of direction provided by the inventor is poor, because the

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applicant does not synthesize or test compounds where R1, R8, R14, , R19, R20, R4-R7 are equal to any of heteroaryl rings claimed, and where R19 and R20 come together to form any of the heteroaryl rings claimed. The applicant does not test the whole breadth of compounds encompassing all of the moieties that these particular radicals can be. In terms of the 8<sup>th</sup> Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicant does not describe how precursor group R3 can be changed to a group R3, how an R3 group can be changed to a different R3 group, and whether the end product R3 is different from the precursor R3.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim(s) 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 7 is indefinite for being improper product use claims. Applicant is referred to Clinical Products v. Brenner -Commissioner of Patents) 149 USPQ 475 (District Court DC 66) Ex parte Dunki 153 USPQ 678 (Bd of Appeals 1967).

B. Claim 7 recites the limitation of several provisions in lines 3-10, page 69 of claim 7, as well as the term "Formula (1A)" in line 2 of claim 7, page 3. There is insufficient antecedent basis for these limitations in the claim.

C. In claim 10, the phrase "if desired or necessary", in line 10, page 70, is indefinite.

D. In claim 10, line 6 and line 11, the term "precursor" is indefinite. What precursors is the applicant claiming?

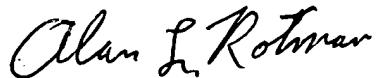
The IDS at papers no. 7, 8, 9 have been considered. The references that have been crossed out will not be considered until the applicant provides the examiner with the references.

The elected species is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.



Binta Robinson

ALAN L. ROTMAN  
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August 10, 2003